BD MAX™ ExK™ DNA-1

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REF 442817

Plasma, Serum or Neat Urine
For use with the BD MAX™ System

P0121(06)
2014-08

2°C 25°C

IVD

INTENDED USE

The BD MAX™ ExK™ DNA-1 is intended to extract DNA from plasma, serum or neat urine specimens. The DNA Extraction Tube contains a Sample Processing Control sequence from *Drosophila melanogaster* (GenBank: AC246436; nucleotides 35779 to 35978) cloned in a pUC119 derivative (GenBank: U07650.1). The BD MAX™ ExK™ DNA-1 has not been validated for use with any specific test method.

PRINCIPLES OF THE PROCEDURE

The specimen is mixed with the BD MAX™ Sample Buffer Tube and processed using the BD MAX™ System. The BD MAX™ System automates sample lysis, DNA extraction and concentration, reagent rehydration, nucleic acid amplification and detection of the target nucleic acid sequence using real-time polymerase chain reaction (PCR). The BD MAX™ System contains a combination of lytic and extraction reagents designed to perform cell lysis and DNA extraction. Following cell lysis, the released DNA is captured by magnetic affinity beads. The beads with the bound DNA are washed and then the DNA is eluted using 12.5 µL of Elution Buffer. The solution may be prepared for PCR using Neutralization Buffer from the Unitized Reagent Strip. The eluted DNA may be used for applications on the BD MAX™ System or another PCR Amplification/Detection System.

REAGENTS

REF	COMPONENT NAME	QUANTITY
442817	BD MAX™ Extraction Tubes (A8) Dried extraction reagent containing magnetic affinity beads, Proteinase K and Sample Processing Control	Σ 24
	BD MAX™ Sample Buffer Tube (SB-1) (with 25 septum caps)	
	BD MAX™ DNA Reagent Strip (S05) Unitized Reagent Strip containing all liquid reagents and disposable pipette tips necessary for specimen processing and DNA extraction	
	BD MAX™ Conical Tubes	

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ System: REF 441916 or 441927
- Micropipettes (accurate between 2 and 1000 µL)
- Aerosol resistant micropipette tips
- Disposable gloves/lab coat
- Specimen collection container(s)
- PCR Cartridges (REF 437519), if applicable
- BD MAX™ DNA MMK (SPC) (REF 442829) or BD MAX™ DNA MMK (REF 442848), if applicable
- BD MAX™ Conical Tubes (REF 437016), if applicable

WARNINGS AND PRECAUTIONS

- The BD MAX ExK DNA-1 is for *in vitro* diagnostic use.
- Extraction of neat urine specimens using a lysis temperature other than 62°C may decrease DNA extraction efficiency. Select <ExK DNA-1 (Urine)> from the pull down menu of the Worklist, as selection of <ExK DNA-1 (Plasma/Serum)> will result in an incorrect lysis temperature of 37°C.
- Do not use expired reagents and/or materials.
- Do not use the kit if the label that seals the outer box is broken upon arrival.
- Do not use reagents if the protective pouches are open or broken upon arrival.
- Do not use reagents if desiccant is not present or is broken inside reagent pouches.

- Do not remove desiccant from reagent pouches.
- Close protective pouches of reagents promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing.
- Protect reagents against heat and humidity. Prolonged exposure to humidity may affect product performance.
- Do not use reagents if the foil has been broken or damaged.
- Do not mix reagents from different pouches and/or kits and/or lots.
- Do not interchange or reuse caps, as contamination may occur and compromise test results.
- Check Unitized Reagent Strips for proper liquid fills (ensure that the liquids are at the bottom of the tubes) (refer to Figure 1).
- Check Unitized Reagent Strips to ensure that all pipette tips are present (refer to Figure 1).
- Proceed with caution when using chemical solutions as Extraction Tube barcode readability may be altered.
- Good laboratory technique is essential for the proper use of this product. Extreme care should be taken to preserve the purity of all materials and reagents.
- In cases where other PCR tests are conducted in the same general area of the laboratory, care must be taken to ensure that the BD MAX DNA-1, any additional reagents required for testing, and the BD MAX System are not contaminated. Avoid microbial and ribonuclease (RNase)/deoxyribonuclease (DNase) contamination of reagents at all times. The use of sterile RNase/DNase-free disposable aerosol resistant or positive displacement pipette tips is recommended. Use a new tip for each specimen. Gloves must be changed before manipulating reagents and cartridges.
- To avoid contamination of the environment by amplicons, do not break apart the BD MAX™ PCR Cartridge after use. The seals of the BD MAX™ PCR Cartridges are designed to prevent contamination.
- The laboratory should routinely perform environmental monitoring to minimize the risk of cross-contamination.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in CLSI Document M29[1] and in Biosafety in Microbiological and Biomedical Laboratories[2].
- Wear protective clothing and disposable gloves while handling all reagents.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth.
- Do not smoke, drink, chew or eat in areas where specimens or kit reagents are being handled.
- Dispose of unused reagents and waste in accordance with local, state, provincial and/or federal regulations.
- Consult the BD MAX™ System User's Manual[3] for additional warnings, precautions and procedures.

STORAGE AND STABILITY

- BD MAX™ ExK™ DNA-1 components are stable at 2 - 25 °C through the stated expiration date. Do not use if expired.
- The BD MAX™ DNA Extraction Tubes (A8) are provided in sealed pouches. To protect product from humidity, immediately re-seal after opening. The Extraction Tubes are stable for up to 7 days at 2 - 25 °C after initial opening and re-sealing of the pouch.

INSTRUCTIONS FOR USE

Specimen Collection

1. Collect specimen and label appropriately.
   Note: Plasma specimens must be obtained from sodium citrate or EDTA anticoagulated blood. Other anticoagulants have not been evaluated.
2. Collected specimens should be maintained per the conditions validated by the user.
3. Proceed to Extraction Preparation.

Extraction Preparation:

Note: The following extraction preparation procedures are provided as guidance. Some specimens may require pre-processing. Application-specific extraction preparation procedures should be developed and validated by the user.

1. Pipette 750 µL of specimen into a BD MAX™ DNA Sample Buffer Tube SB-1 and close the tube with a septum cap. Ensure complete mixing by vortexing the sample.
2. Proceed to BD MAX™ System Operation.

BD MAX™ System Operation

Note: Refer to the BD MAX™ System User's Manual[3] for detailed instructions (Operation section).

1. Power on the BD MAX System (if not already done) and log in by entering <user name> and <password>.
2. Gloves must be changed before manipulating reagents and cartridges.
3. Remove the required number of Unitized Reagent Strips from the BD MAX™ ExK DNA-1 kit. Gently tap each strip onto a hard surface to ensure that all the liquids are at the bottom of the tubes.
4. Remove the required number of Extraction Tube(s) and Master Mix Tube(s) (if applicable) from their protective pouches. Remove excess air, and close pouches with the zip seal.
5. For each specimen to be tested, place one (1) Unitized Reagent Strip on the BD MAX™ System Rack, starting with Position 1 of Rack A. Assemble the strip as follows:
   Note: A tube is fully seated in the strip when a 'click' is heard. Refer to Figure 1 for reagent placement in the Unitized Reagent Strip.
   a) <u>Extraction only:</u>
      - Position 1 = Snap the DNA Extraction Tube into position 1.
      - Position 2 = Leave position 2 empty.
      - Position 3 = Snap a BD MAX™ Conical Tube into position 3.

b) Type 1: BD MMK or MMK(SPC) and Dried Primers and Probes:
- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap the BD MAX™ DNA MMK (SPC) or BD MAX™ DNA MMK Master Mix Tube into position 2.
- Position 3 = Snap a BD MAX™ Conical Tube containing dried-down primer and probe mixture (at a final concentration of 2X) into position 3.

c) Type 2: BD MMK or MMK(SPC) and Liquid Primers and Probes:
- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap the BD MAX™ DNA MMK (SPC) or BD MAX™ DNA MMK Master Mix Tube into position 2; follow the instructions for use accompanying that product.
- Position 3 = Snap a BD MAX™ Conical Tube into position 3. Pipette 12.5 µL of user supplied primer and probe mixture (at a final concentration of 2X) into the bottom of the Conical Tube in position 3.

d) Type 3: Liquid MM with Primers and Probes:
- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Leave position 2 empty.
- Position 3 = Snap a BD MAX™ Conical Tube into position 3. Pipette 12.5 µL of the user supplied master mix, primer and probe mixture (at a final concentration of 2X) into the BD MAX™ Conical Tube in position 3.

e) Type 4: Lyophilized MM with Primers and Probes:
- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap a BD MAX™ Conical Tube containg user-supplied lyophilized master mix in position 2.
- Position 3 = Snap a BD MAX™ Conical Tube into position 3. Pipette 12.5 µL of user-supplied rehydration buffer into the BD MAX™ Conical Tube in position 3.

6. Click on the Run icon and enter the kit lot number for the BD MAX ExK DNA-1 (for lot traceability) by either scanning the barcode with the scanner or by manual entry.
   Note: Repeat step 6 each time a new kit lot is used.
7. Navigate to the Worklist. Using the pull down menu select <ExK DNA-1 (Plasma/Serum)> if testing plasma or serum specimens, or <ExK DNA-1 (Urine)> if testing neat urine.
   Note: Take care to select the correct assay from the pull down menu as the default lysis temperatures differ between Plasma/Serum and Urine specimens. The default lysis temperature for Plasma/Serum is 37°C whereas the default lysis temperature for Urine is 62°C.
8. Enter the Sample Buffer Tube ID, Patient ID and Accession Number (if applicable) into the Worklist, either by scanning the barcode with the scanner or by manual entry.
9. Select the appropriate kit lot number (found on the outer box) from the pull down menu.
10. Repeat Steps (7-9) for all remaining Sample Buffer Tubes.
11. Place the Sample Buffer Tubes in the BD MAX System Rack(s) corresponding to the Unitized Reagent Strips assembled in step 5.
    Note: Place the Sample Buffer Tubes in the sample rack(s) with the 1D barcode labels facing outward (this makes scanning Sample Buffer Tubes easier during sample login).
12. If the BD MAX™ System is also being used for DNA amplification, place the required number of BD MAX™ PCR Cartridge(s) into the BD MAX System (see Figure 2).
    - Each cartridge accommodates 2 runs of up to 12 samples for a total of 24 samples.
    - The BD MAX System will automatically select the position and row on the PCR Cartridge for each run.
    - PCR Cartridges are used on a per-run AND rack basis (2 runs per cartridge and 1 cartridge per rack).

Figure 1: BD MAX™ Unitized Reagent Strip

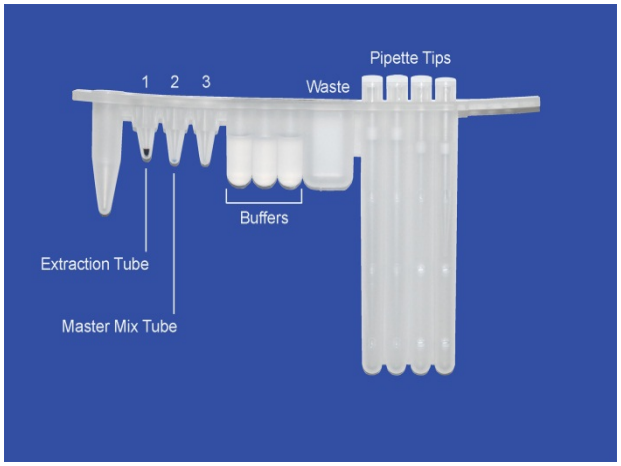
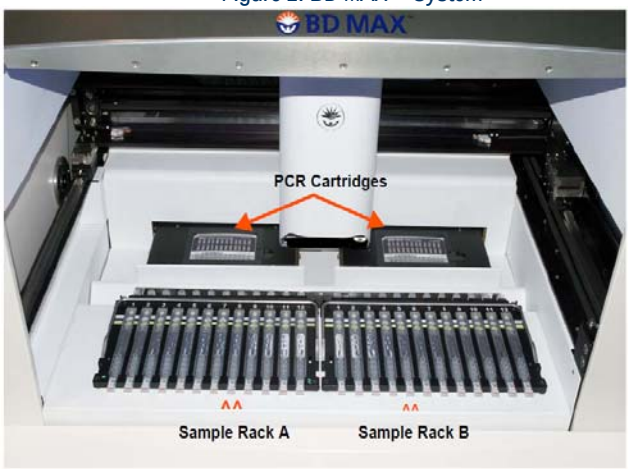


Figure 2: BD MAX™ System



13. Load rack(s) onto the BD MAX™ System (Figure 2).
14. Close the BD MAX™ System lid and click <Start> to begin processing.

LIMITATIONS OF THE PROCEDURE

1. The BD MAX™ ExK™ DNA-1 can only be used on the BD MAX™ System by trained personnel.
2. Use of the BD MAX™ ExK™ DNA-1 for clinical specimen types other than those specified have not been validated.
3. Plasma obtained from blood anticoagulated by methods other than sodium citrate and EDTA have not been validated.
4. Use of BD MAX™ ExK™ DNA-1 for neat urine specimens has only been validated with a lysis temperature of 62°C. Select <ExK DNA-1 (Urine)> from the pull down menu of the Worklist, as selection of <ExK DNA-1 (Plasma/Serum)> will result in an incorrect lysis temperature of 37°C.
5. The selected application of this product must be validated by the user. Validations should be performed in accordance with country, federal, provincial, state, local and/or accrediting organization guidelines, regulations and standards.

REFERENCES

1. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
2. Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in microbiological and biomedical laboratories. Chosewood L.C. and Wilson D.E. (eds) (2009). HHS Publication No. (CDC) 21-1112.
3. BD MAX™ System User's Manual (US Open System version 8089571 or International version 8089570 refer to the latest revision) BD Diagnostics, Sparks, MD USA.

	Temperature limitations		Perforation
	Manufacturer	LOT	Batch code (Lot)
REF	Catalog number		Use by / YYYY-MM-DD / YYYY-MM (MM = end of month)
IVD	In vitro Diagnostic Use Medical Use	Σ	Contains sufficient for <n> tests
	Keep dry		Consult Instructions for Use

This product is sold under license, and purchase of this product does not include rights to use for certain blood and tissue screening applications, nor for certain industrial applications.

BD

Technical Information: In the United States, contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com/ds.

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